



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 6, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-35

Richard Hicks
Freedomantiviral
12221 NE 70th Street
Kirkland, WA 98033

WARNING LETTER

Dear Mr. Hicks:

This letter concerns your firm's marketing of the products Fix-It Antiviral, Fix-it Oral Antiviral, Pre-Fix Invisible Condom, and Acyclovir. According to information on your website, www.freedomantiviral.com, Fix-It Antiviral is sold as a topical antiviral drug product for the treatment of herpes; Fix-it Oral Antiviral is marketed as an oral antiviral drug product for the treatment of herpes, flu, cold, and other viral infections; and Pre-Fix Invisible Condom is sold as a topical antiviral for the prevention of sexually transmitted diseases such as human immunodeficiency virus (HIV), herpes, human papilloma virus (HPV), gonorrhea, chlamydia, genital warts, and other sexually transmitted diseases. You also offer the product Acyclovir, an approved, antiviral prescription drug for the treatment of herpes, chickenpox, shingles, and other conditions, without a prescription.

You state on your website that Fix-It Antiviral cream "Heals and prevents herpes outbreaks," and that "Fix-It Antiviral Herpes Treatment is a topical antiviral cream that penetrates deep into the dermis and inactivates the herpes virus within human cells. It completely prevents lesions if used before they form, and dramatically reduces healing time if used once they are visible. It stops viral shedding, and can be used regularly to prevent outbreaks. Can be used for HSV type 1 and 2; oral or genital herpes."

Your website also states that "Fix-it Oral Antiviral is a blend of 20 active ingredients concentrated from natural organic sources that have each been clinically proven to speed healing from herpes outbreaks or prevent outbreaks altogether. Fix-it Oral Antiviral can be used as a suppressive treatment, or when herpes outbreaks may occur. May be used alone or in conjunction with Fix-it Antiviral topical cream." The site further states that "Fix-it Oral Antiviral is also effective against other viral infections, such as cold and flu."

Richard Hicks
Freedomantiviral, 12033 NE 80th Kirkland, WA 98033
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Regarding Pre-Fix Invisible Condom, your site states, "Pre-Fix is a high quality anti-viral sexual lubricant gel that helps to prevent the transmission of all sexually transmitted diseases, including HIV and Herpes. Pre-Fix also acts as a spermicide." The site further claims, "Clinical studies have demonstrated that these ingredients are effective in preventing STD transmission in both animal and human trials. We believe the synergy of these active ingredients make Pre-fix Invisible Condom the most powerful and effective STD prevention product available. Pre-Fix can help to prevent the transmission of Herpes, HIV virus that causes Aids [sic], Genital Warts, HPV, Chlamidia [sic], Gonorrhea, and other STDs. Freedomantiviral, "Pre-Fix can also be applied inside the vagina up to one hour before sex to reduce the risk of STD transmission. In an emergency it may also be applied after sex, but this is less effective."

Your website states that "Acyclovir is an antiviral used to treat shingles, chickenpox, or genital herpes. It may also be used to treat other conditions."

Fix-It Antiviral, Fix-it Oral Antiviral, and Pre-Fix Invisible Condom are "drugs," as defined by 21 U.S.C. § 321(g), because they are promoted to cure, mitigate, treat, or prevent disease. Moreover, these products are "new drugs," as defined by 21 U.S.C. § 321(p), because there is no evidence that they are generally recognized as safe and effective for their intended uses. Under 21 U.S.C. § 355(a), a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. The distribution of Fix-It Antiviral, Fix-it Oral Antiviral, and Pre-Fix Invisible Condom for these intended uses without an approved NDA violates 21 U.S.C. § 331(d).

Furthermore, the conditions for which these products are offered are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these drugs safely for their intended purposes. Thus, all three products' labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under 21 U.S.C. § 352(f)(1).

The drug Acyclovir is misbranded within the meaning of 21 U.S.C. § 353(b)(1) in that it is not dispensed pursuant to the prescription of a practitioner licensed by law to administer it.

The above violations are not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that the drug products you manufacture and/or distribute meet all of the requirements of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

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Freedomantiviral, 12033 NE 80th, Kirkland, WA 98033
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You must immediately correct these violations. If you do not immediately correct them, we are prepared to take enforcement action against you without further notice. The Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products. Individuals and businesses that violate the Act may also be subject to criminal prosecution.

You must notify this office in writing within 15 working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations, and the steps taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made.

Address your reply to the U.S. Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021-4421, Attention: Michael J. Donovan, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', written over a horizontal line.

Charles M. Breen
Director, Seattle District

Cc:

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